DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 22, 2014

Wright Medical Technology, Inc.
Val Myles
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K142602
Trade/Device Name: VALOR® Hindfoot Fusion Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 26, 2014
Received: September 30, 2014

Dear Ms. Val Myles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142602

Device Name
VALOR HINDFOOT FUSION NAIL SYSTEM

Indications for Use *(Describe)*
The VALOR® Hindfoot Fusion Nail System is intended to facilitate tibiotalocalcaneal arthrodesis in any of the following indications:
- Severe foot/ankle deformity,
- Osteoarthritis,
- Instability and skeletal defects after tumor resection,
- Neuro-arthropathic deformity or Charcot deformity,
- Avascular necrosis of the talus,
- Revision of a failed joint replacement or failed ankle fusion,
- Distal tibia fracture and non-unions,
- Rheumatoid arthritis and pseudoarthosis

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Headquarters
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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the VALOR® Hindfoot Fusion Nail System.

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1. **Submitted By:** Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Date: September 12, 2014

Contact Person: Val Myles
Regulatory Affairs Specialist
Office (901) 867-4120
Fax (901) 867-4190

2. **Proprietary Name:** VALOR® Hindfoot Fusion Nail System

Common Name: Ankle Fusion Nail

Classification Name and Reference: 21 CFR 888.3020- Class II

Device Product Code, Device Panel: HSB: Rod, Fixation, Intramedullary and Accessories

3. **Predicate Device:** K090857 VALOR® Ankle Fusion Nail System

4. **Device Description**

The design features of the subject VALOR® Hindfoot Fusion Nail System are summarized below:

- Nails and screws are manufactured from titanium alloy.
- Nails are available in two diameters and a range of lengths.
- Screws are available in one diameter and a range of lengths.

The subject nail in this Special 510(k) is a line extension of the system to include a 300mm length nail. The design features of the VALOR® Hindfoot Fusion Nail System are substantially equivalent to the design and features of other the devices in this product family previously cleared for market.

5. Intended Use

The VALOR® Hindfoot Fusion Nail System is intended to facilitate tibiotalocalcaneal arthrodesis in any of the following indications:

- Severe foot/ankle deformity,
- Osteoarthritis,
- Instability and skeletal defects after tumor resection,
- Neuro-arthropathic deformity or Charcot deformity,
- Avascular necrosis of the talus,
- Revision of a failed joint replacement or failed ankle fusion,
- Distal tibia fracture and non-unions,
- Rheumatoid arthritis and pseudoarthosis

6. Technological Characteristics Comparison

The VALOR® Hindfoot Fusion 300mm Nail System compared the legally marketed predicate device is 50mm longer. No changes have been made to any other dimensions or materials.

7. Substantial Equivalence- Non-Clinical Evidence

The subject 300mm nails do not provide a new worst case. From testing parameters performed on the predicate device, the 300mm nail will perform the same as the predicate in worst case testing because the working length and diameters have remained unchanged from the 250mm to 300mm nails.

8. Substantial Equivalence- Clinical Evidence

N/A

9. Substantial Equivalence- Conclusions

The design characteristics of the subject devices do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.